

MEDICAL LABORATORY BOARD MINUTES

Date: January 13, 2005

Time: 9:00 a.m., CST

Location: Cumberland Room
Ground Floor, Cordell Hull Building
425 Fifth Avenue North
Nashville, TN 37247

Members Present: Kelly S. Terry, MT Chairman
Jere Ferguson, MD, Vice-Chairman
Dennis Carter, MD
Edward McDonald, MD
Thomasa Cooper, Medical Technologist
Martha Duncan, Medical Technologist
Sharon Hargrove, Medical Technologist
Linda Lahr, Medical Technologist
Alison McDonald-Spakes, Cytotechnologist
Debbie Stinnett, Medical Technologist
Delores Voigt, MT Hospital Administrator

Members Absent: Monya Faye Pryor, Citizen Representative

Staff Present: Lynda S. England, Medical Technologist, Director
Cheryl H. Thacker, Medical Technologist, Consultant
Robbie Bell, Health Related Boards Director
Jerry Kosten, Rules Manager
Robert Kraemer, Jr., Advisory Attorney
Onezean Otey, Jr., Medical Technologist Consultant/Surveyor,
East Tennessee Regional Office
Sandra S. Bogard, Medical Technologist Consultant/Surveyor,
Middle Tennessee Regional Office
Irmgard Brown, Medical Technologist Consultant/Surveyor,
Middle Tennessee Regional Office
Karon Daniels, Medical Technologist Consultant/ Surveyor,
West Tennessee Regional Office

Staff Absent: Julia Daniels, Medical Technologist Consultant/ Surveyor
East Tennessee Regional Office
Mary Hamblen, Medical Technologist Consultant/Surveyor
West Tennessee Regional Office

Quorum:

A sufficient number of board members were present to constitute a quorum.

Election of Board Chairman:

Ms. Lahr nominated Ms. Terry to be the chairman for the 2005 calendar year. A second to that motion was made by Dr. Ferguson. The motion carried.

Presiding Officer:

The meeting was called to order by Chairmen, Kelly S. Terry at 9:00 a.m. Board Members introduced themselves to the audience.

Board Member Resignation:

Charles R. Handorf, MD board member since 1994 has resigned his position effective December 30, 2004 citing a scheduling conflict. Dr Handorf filled the statute required Pathologist/Educator appointed position.

Board Minutes:

A motion to approve the October 14, 2004 Full Board minutes was made by Ms. Stinnett with a second to the motion by Dr. McDonald. The minutes were approved.

A motion to approve the Personnel & Education Committee minutes from the October 13, 2004 meeting was made by Dr. McDonald. A second to the motion was made by Ms. Voigt. The Committee minutes were approved.

Board Report-Personnel & Education Committee:

Linda Lahr, MT
Committee Chair

Ms. Lahr presented report of actions from the Personnel & Education Committee meeting held on January 12, 2005. A motion to accept this report was made by Dr. Ferguson. A second to the motion was made by Dr. McDonald. The motion carried and the actions of the Committee were ratified.

Board Report-Tennessee Professional Peer Assistance Program:

Mike Harkreader, MA, RN
TNPAP State Director

Mr. Harkreader gave the report from this advocacy agency concerning medical laboratory professionals. A total of 27 licensees have utilized this program since the beginning of the contract period.

Mr. Harkreader also expressed the desire to have the TNPAP educational materials, video and power point presentation consider as a mechanism for continuing education credits for med lab

professionals. This suggestion will be considered by the board and administrative staff. A motion to approve this report was made by Ms. Duncan with a second to the motion by Ms. Stinnett. The motion carried

A copy of Mr. Harkreader's report is on file in the Board's administrative office.

Ms. Hargrove made a motion to amend the TNPAP contract for the year 2005-2006. A second to that motion was made by Dr. McDonald. The motion carried.

Board Report-Rules:

Jerry Kosten-Rules Manager

A. Rules Amendments:

Mr. Kosten reported on a rulemaking hearing held December 17, 2004 concerning the following amendments to:

- 1- Rule 1200-6-1-.09 regarding the renewal of personnel licenses and
- 2- Rule 1200-6-1-.11 regarding retirement and reactivation of personnel licenses and
- 3- Rule 1200-6-1-.13 regarding temporary license for medical laboratory personnel and
- 4- Rule 1200-6-3-.08 regarding patient test management and
- 5-Rules 1200-6-1-.12 regarding continuing education for medical laboratory personnel.

There were three written comments to this proposed rule change. The board discussed these comments and responded with several suggested modifications to the rules. A motion to accept the changes was made by Ms. Hargrove with a second by Ms. Cooper. These changes to the rules based on the rulemaking hearing comments were adopted.

A motion to adopt these amendments was made by Ms. Lahr with a second to the motion by Ms. Voigt. The motion carried.

A roll call vote was taken with all members present voting aye.

B. Authorize Rulemaking Hearing:

The board authorized a rulemaking hearing to be held March 24, 2005 for:

- 1- Mandatory criminal background checks for all new applicants and
- 2- Rules 1200-6-3-.16 concerning health screens and

3- National certification agency name change from National Committee for Clinical Laboratory Standards (NCCLS) to Clinical & Laboratory Standards Institute (CLSI).

A motion to authorize a rulemaking hearing for Item 1 was made by Dr. McDonald with Ms. Lahr providing a second to the motion. The motion carried.

A motion to authorize a rulemaking hearing for Item 2 & 3 was made by Dr. Carter with a second to this motion by Dr. Ferguson. The motion carried.

Contested Case:

There was no contested case during this board meeting.

Ratifications:

The following items were presented to the Board for ratification per staff, state surveyor or facility request:

- 1) Exemptions for point of care testing procedures (POCT) in a licensed facility (See Attachment 1).
- 2) Initial licenses for Clinical Laboratory Facilities (See Attachment 2).

Board Director's Report/Discussion:

Lynda S. England BS MT(ASCP)
Director

Ms. England reported quarterly administrative office/staff activities to the Board members. This report included administrative office statistics, contact with TNPAP for peer assistance services, upcoming rulemaking hearings, legislative actions, website updates, and facility closures. The complete report is on file in the administrative office.

A motion to accept Ms. England's report was made by Ms. Cooper, with a second to the motion by Dr. McDonald. The motion carried.

**Direct More Than Three (3) Labs
Rule 1200-6-3-.13(5) Medical Lab Facilities:**

There were no requests presented to the board for review during the January meeting.

Reinstatement of License:

There were no requests for licenses to be reinstated during this meeting.

Reports/Discussion:

1-Regional Consultant/Surveyor – Proficiency Testing (PT)
Complaints on Licensed Laboratory Facilities

A. East Tennessee Regional Office-Onezean Otey, Consultant I/Surveyor

Unsatisfactory or Unsuccessful Proficiency Testing:

Proficiency testing issues were addressed with three (3) licensed facilities to include the first unsuccessful participation for the following:

PTT-incorrect reagent code and/or did not complete PT reporting form

HCT-random error with quality control and quality assurance records/no patient results affected.

Parasitology-testing discontinued due to low volume with no patients reported during the cycles proficiency testing was performed.

Complaints:

There was zero (0) complaint reported during the last quarter of 2004.

B. Middle Tennessee Regional Office- Sandra S. Bogard, Consultant II/Surveyor
Irmgard A. Brown, Consultant I/Surveyor

Unacceptable/Unsuccessful Proficiency Testing:

The number of licensed laboratories demonstrating a first occurrence of unsuccessful proficiency testing events (two out of three events) is zero (0):

The number of state licensed laboratories with second (2nd) occurrence of unsuccessful proficiency testing events (three out of four/three in a row): none (0).

Complaints:

The Middle Tennessee Regional Office has conducted one (1) complaint investigation during this quarter. The complaint was substantiated with an acceptable plan of correction.

C. West Tennessee Regional Office-Karen Daniels, Consultant I/Surveyor

Unacceptable/Unsuccessful Proficiency Testing:

The number of state licensed laboratories with a first occurrence of unsuccessful proficiency testing (two out of three or two in a row): two (2).

The number of state licensed laboratories with second occurrence of unsuccessful proficiency testing (three out of four or three in a row): zero (0).

Complaint Investigations:

There were zero (0) complaint investigations from the West Tennessee Regional Office this quarter.

A motion to approve all three (3) of these reports was made by Dr. Ferguson with a second to the motion by Dr. Carter. The motion carried.

2-Kelly Cupp, CT(ASCP), MT(ASCP)
Team Director of Laboratory Services
Innovative Pathology Services, PLLC
Knoxville, TN

Ms. Cupp made an appearance before the board concerning clarification of:

The results of “within normal limits” Pap smear (Cytology-Gyn) being mailed by the contracting laboratory to the ordering physician “pap notification cards”

Phone lines to this laboratory with patients receiving reports via utilization of a PIN number.

Tennessee Code Annotated §68-29-121(b) in that the “results of a laboratory test shall be reported to the physician, optometrist, dentist, chiropractic physician or other health care professional who requested it.”

The suggestion was made that the laboratory contract with the authorizing physician to allow the laboratory to send the results **for the physician** (the laboratory acts as an agent of the physician). Another board suggestion was to have the laboratory send the test results to the physician and the physician mail the results to the patient.

Health Related Board’s Report/Discussion:

Robbie Bell, Director

Ms. Bell did not make a report to the board during this meeting.

Office of General Counsel Report:

Robert J. Kraemer, Jr.
Advisory Attorney

Mr. Kraemer led the discussion of the following items:

1. **Temporary Permits & Cleanup (04-1037)** The rulemaking hearing was held on March 19, 2004; this amendment was adopted by the Board on April 15, 2004 and was sent to the Attorney General on April 22, 2004. The amendment was signed by the Attorney General and filed with the Secretary of State on October 22, 2004 and became effective December 25, 2004.

2. **Hematology Controls (04-1192)** The rulemaking hearing was held on July 8, 2004 and the Board adopted the amendment on July 15, 2004. It went to the Attorney General on July 21, 2004 and is still there.
4. **Screening Tests and Civil Penalties (04-1378)** The rulemaking hearing was held on September 23, 2004 and this amendment was adopted by the Board on October 14, 2004. It was sent to the Attorney General on January 27, 2004 and is still there.
5. **Continuing Education, Temporary Licensure & Lab Test Orders (04-1554)** The rulemaking hearing was held on December 17, 2004 and after the Board's response to comments, these amendments are ready for adoption at this meeting.

Litigation:

The Office of General Counsel currently has seven (7) open disciplinary cases pertaining to the Medical Laboratory Board.

A motion to accept this report was made by Dr. McDonald with a second by Ms. Voigt. The motion carried.

Bureau of Investigations (BIV) Report:

Lea Phelps
Disciplinary Coordinator

Documentation was presented for board review concerning the number of cases in the Bureau of Investigation.

Ms. Phelps distributed the disciplinary report to the Board members, noting that the list comprised disciplinary actions on licensees beginning in July 1996 through November 2001.

A motion to accept this report was made by Ms. Lahr with a second to the motion made by Ms. McDonald-Spakes. The motion carried.

Office of Health Licensure & Regulation:

Judy Eads, RN
Assistant Commissioner of Health

Ms. Eads did not make a report at this time.

Financial Report:

Lisa Tittle
Fiscal Officer

A copy of this report is on file in the administrative office.

Waived Testing Procedures:

A motion to add the Clinitest Tablet for Reducing Substances (urine/stool) CPT 84999 to the Point of Care Waived Test List was made by Ms. Hargrove with a second to the motion by Ms. Lahr. The motion carried.

Point of Care Task Force:

This task force continues to meet but no inquiries were made to the board during this meeting.

Review Eligibility of Medical Laboratory Director:

1. James L. Prescott, Ph.D.
Knoxville, TN 37918
Director-Molecular Diagnostics

Ms. Thacker informed the Board Dr. Prescott's file was complete and he has met the requirements for licensure in the category of Director of Molecular Diagnostics. The applicant holds a Ph.D. degree in the clinical specialty of molecular biology and possesses national boarding in Molecular Diagnostics from the American Board of Bioanalysis. Dr. Ferguson made a motion to approve this application. A second to the motion was made by Ms. Voigt. The motion carried.

2. Frank K. Fujimura
Calabasas, CA
Director-Molecular Diagnostics

Ms. Thacker informed the Board Dr. Fujimura holds a Ph.D. in Biology and is boarded by the American Board of Medical Genetics. A motion to approve this application contingent on transcripts being received in the administrative office was made by Ms. Hargrove with a second to the motion by Ms. Lahr. The motion carried for licensure as a Director-Molecular Diagnostics.

Other Business:

Statement of Next Meeting:

The next meeting will be held on April 14, 2005 beginning at 9 am, CDT in the Cumberland Room, Ground Floor Cordell Hull Building, 425 Fifth Avenue North, Nashville, TN 37247-1010.

Record of Adjournment

With no further business to discuss, the meeting was adjourned at 1:00 p.m. on a motion properly presented by Ms. Duncan and seconded by Ms. McDonald-Spakes. The motion carried.

Kelly S. Terry, MT
Board Chairman

Date

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REQUEST FOR EXEMPTION-POINT OF CARE TESTING PROCEDURES

1. Wellmont Holston Valley Medical Center
130 West Ravine Road
Kingsport, TN 37660

Facility Representative: Richard Doyle
Laboratory Manager

This facility request was for:

- 1 - Registered Nurses (RN's) and Respiratory Therapists to perform and report measured blood gases, pH, sodium, potassium, glucose, chloride, ionized calcium, lactate, hematocrit & hemoglobin with associated parameters in the Cardiac Intensive Care Unit utilizing the GEM Premier 3000 instrument and methodologies.

A motion to approve this request was made by Dr. McDonald with a second to the motion by Ms. Hargrove. The motion carried.

Dr. Ferguson and Ms. Lahr recused themselves from the discussion and vote.

- 2 - Registered Nurses (RN's) and Certified Registered Nurse Anesthesiologists (CRNA's) to perform and report measured blood gases, pH, sodium, potassium, chloride, ionized calcium, glucose, hematocrit, lactate and hemoglobin, Surgery Department utilizing the GEM Premier 3000 instrument and methodologies.

A motion to approve this request was made by Dr. McDonald. A second to the motion was made by Dr. Carter. The motion carried.

Dr. Ferguson and Ms. Lahr recused themselves from the discussion and vote.

2. The Jackson Clinic, P.A.
616 West Forest Avenue
Jackson, TN 38301

Facility Representative: Donna Morse, MT

This facility request was for Phlebotomists to perform and report hemoglobin A1C's utilizing the Bayer DCA 2000 instrument and methodologies. The phlebotomists will be supervised daily by a licensed technologist monitoring maintenance, quality control and performance.

A motion to approve this request was made Dr. McDonald with a second to the motion by Ms. Stinnett. Ms. Lahr voted nay. The motion carried.

3. Johnson City Medical Center
400 State of Franklin Road
Johnson City, TN 37604

Facility Representative: Karen Cox, MT
Point of Care Coordinator

This facility made the following exemption requests:

- 1 - Anesthesia Tech II's in the Open Heart Surgical Suites, Surgical Suites & Same Day Surgery Center to perform and report blood gases, ionized calcium, sodium, potassium, chloride, glucose, BUN/urea, hematocrit and calculated hemoglobin utilizing the i-STAT instrument and methodologies.

A motion to approve this request was made by with a second to the motion by Dr. Ferguson with a second to the motion by Dr. McDonald. The motion carried.

- 2 - Licensed Registered Nurses (RN's), Licensed Practical Nurses (LPN's) and Radiologic Technologists to perform and report blood urea nitrogen (BUN) and creatinine analyses in the Radiology Department utilizing the i-STAT instrument and methodologies.

A motion to approve this request was made by Ms. Hargrove with a second to the motion by Dr. Ferguson. The motion carried.

4. Cookeville Regional Medical Center
142 West Fifth Street
Cookeville, TN 38501

Facility Representative: Christopher Brown, MT
Point of Care Coordinator

This request was for Registered Nurses (RN's) to perform and report activated clotting times (ACT's) in the Cardiothoracic Surgical Suite utilizing the Actalyke Clotting Time Test System.

A motion to approve this request was made by Dr. McDonald. A second to the motion was made by Ms. Hargrove. The motion carried.

5. Diagnostic Laboratories-VUMC
22nd & Pierce 4605 TVC
Nashville, TN 37232-5310

Facility Representative: Terry Tubb, MT
Point of Care Coordinator

This exemption request was for Certified Heart Station Technicians to perform and report platelet aggregation studies utilizing the Accumetrics Ultegra System (Accumetrics VerifyNow Aspirin Assay) in the Vanderbilt Page-Campbell Heart Institute.

A motion to approve this request was made by Dr. Ferguson with a second to the motion by Ms. Hargrove. Ms. Lahr voted nay. The motion carried.

Ms. Tubb was requested to return to the board meeting in July 2005 to provide a performance report on this exemption.

6. Gateway Health System
1771 Madison Street
Clarksville, TN 37043

Facility Representative: Mary Bowles BSMT(ASCP), BSN RN
Point of Care Coordinator

This facility requested Licensed Nurses (RN's & LPN's), Nurse Practitioners, EMT-Paramedics, Physician Assistants and Medical Assistants to perform and report urine pregnancy testing procedures in the Occupational Health Department utilizing the Beckman Coulter ICON 25hCG test kit.

This test kit methodology is CLIA waived and is included in the Board's point of care waived test menu. No action was taken.

7. The Regional Medical Center at Memphis
877 Jefferson Avenue
Memphis, TN 38103

Facility Representative: Seth L. Daniel MT(ASCP) BS
Point of Care Coordinator

This facility made a request to exempt the following procedures:

- 1 - Registered Cardiac Invasive Specialists to perform and report activated clotting times (ACT's) in the Cardiac Cath Laboratory utilizing the Hemochron, Jr. Signature instrument and methodologies.

A motion to approve this request was made by Dr. Ferguson. A second to the motion was made by Dr. McDonald. The motion carried.

2-Registered Cardiac Invasive Specialists to perform and report whole blood oximetry in monitoring O₂ Saturation, O₂ Content and Total Hemoglobin utilizing the AVOXimeter 1000E in the Cardiac Cath Laboratory and the Dialysis Laboratory.

A motion to approve this request was made by Dr. McDonald with a second to the motion by Dr. Ferguson. The motion carried.

INITIAL FACILITY LICENSES: REGIONAL SURVEYOR RECOMMENDATION

1. Lifeblood/Mid-South Regional Blood Center
1265 Union Avenue
Memphis, TN 38104

Medical Laboratory Director: Edward Scott, M.D.
American Board of Pathology-Blood Bank

Specialties: Spun Hematocrit

Surveyor: Mary J. Hamblen, MT Consultant II/Surveyor
West TN Regional Office

A motion to approve this request was made by Ms. Hargrove with a second to this motion by Dr. Carter.

The motion carried.

2. Salex Corporation
1740 Highway 411 Unit 4
Vonore, TN 37885

Medical Laboratory Director: James Pickett, M.D.
Anatomic/Clinical Pathology

Specialties: Endocrinology-RIA & ELISA

Surveyor: Onezean Otey, Consultant I/Surveyor
East TN Regional Office

A motion to approve this request was made by Dr. McDonald with a second to the motion by Ms. Cooper. The motion carried.